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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,371	07/16/2002	Amanda Johanne Kiliaan	2001-1027	7395

466 7590 05/20/2003

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ARLINGTON, VA 22202

EXAMINER

KRISHNAN, GANAPATHY

ART UNIT	PAPER NUMBER
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1623

9

DATE MAILED: 05/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/089,371

Applicant(s)

KILIAAN ET AL.

Examiner

Ganapathy Krishnan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-16 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 9-16 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: .

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DETAILED ACTION

The Amendment B filed March 6, 2003 has been received, entered into the record and carefully considered. The following information provided in the amendment affects the instant application:

1. Claims 1-8 have been cancelled without prejudice.
2. New claims 9-16 have been added.
3. Remarks drawn to rejections under U.S.C. 101, 112 and 103.

Claims 9-16 are pending.

The rejections of claims 1-8 under U.S.C. 101 and 112 have been obviated by the cancellation of claims 1-8. The office action on the merits of new claims 9-16 is contained herein below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alsop et al (EP 0153013) in combination with Greenberg (USPN 5,260,279) is being maintained.

Claims 9-15 are drawn to method of reducing uptake of high molecular weight substances, allergens and microorganisms through the intestinal wall comprising

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administering to a mammal a nutritional composition containing at least one polysaccharide selected from the group consisting of dextrans of molecular weight 8kD to 40,000kD, hydrolyzed glucomannans having a molecular weight of 0.5kD to 1000kD and hydrolyzed galactomannans other than guar gum having molecular weight of 0.5kD to 1000kD with the rise in viscosity being less than 10mPa.s; wherein the nutritional composition is a complete food, is a food supplement, wherein the uptake occurs in the intestinal wall; wherein the recipient of the active ingredient suffers from allergies, allergic reactions and inflammatory processes; wherein the composition is administered in a quantity such that the concentration of the polysaccharide in the intestine is 0.1 to 6g/l

Alsop et al teach a composition containing dextrans with a molecular weight of from 10,000 to 50, 000, 000. The composition is indicated for treatment of conditions of the gastrointestinal tract (page 3, lines 20-24). The dextrans have some antibacterial action and the compositions help flow of potentially toxic or allergic substances, enabling these to pass thro the gut before they are absorbed (page 7, lines 12-22). According to Alsop et al, in general, the higher the molecular weight of the dextran the greater will be the viscosity (page 7, lines 4-6). Alsop et al state that the preferred liquid formulations to contain from 0.5 to 7% w/w of dextran (page 5, lines 18-19) and that the dextrans can be incorporated into existing food stuff formulation (a food supplement). Alsop et al also provide examples of compositions, which contain dextrans and other essential vitamins, and minerals, which is a complete food. Alsop discloses that no oligosaccharides (high molecular weight substances) were absorbed in volunteers fed with the dextrans (page 12, line 3).

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Greenberg discloses that the primary requirement for enteral compositions is that the fiber added to the enteral composition should not substantially increase the viscosity of the product (col. 2, lines 20-25).

One of ordinary skill in the art will be motivated to use the teachings of Alsop and Greenberg in a method for reducing the uptake of high molecular weight substances, allergens and microorganisms through the intestinal wall comprising administering a composition containing dextran as instantly claimed. Even though Alsop states that his composition is used to treat constipation by using the bulking effect of dextran, the same composition is also indicated for clearing of toxic or allergic substances and high molecular weight substances from the gut before they are absorbed. The prior art does not limit the recipient to mammals suffering from any specific conditions. The bulking effect is mainly used for treatment of constipation. In view of the teaching of Alsop regarding the correlation between molecular weight and viscosity of dextran compositions and that of Greenberg regarding the viscosity requirement for enteral compositions, one of ordinary skill in the art would be motivated to use these teachings to make a composition having an ideal viscosity and use it in a method for efficient clearing of high molecular weight substances, allergens and microorganisms from the gut, thereby reducing their uptake through the intestinal wall as applicants have done with the above cited references before them.

Applicant's arguments filed March 6, 2003 have been fully considered but they are not persuasive.

Applicants argue that the dextran component and the oral compositions of Alsop are used to treat constipation due to the bulking effect of the dextran and in the instant on

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the contrary the thickening effect is minimized. In Alsop's examples the concentrations are higher since a higher concentration is needed to produce the bulking effect for the treatment of constipation. Alsop also discloses that the higher the molecular weight the higher the viscosity and that the dextran compositions also enable allergic substances to pass through the gut before they are absorbed. Greenberg teaches that the soluble fiber should not substantially increase the viscosity of enteral compositions. Based on these disclosures of Alsop and Greenberg, one of ordinary skill in the art can conclude that for a composition as instantly claimed a lower concentration of dextran is essential for the desired increase or decrease of viscosity which is less than 10mPa.s. and use such a composition in a method for efficient clearing of high molecular weight substances and microorganisms through the gut and thereby reducing their uptake.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Alsop et al (EP 0153013) in combination with Greenberg (USPN 5,260,279) is being maintained.

Claim 16 is drawn a nutritional composition containing dextrans of molecular weight 8kD to 40,000kD with the proviso that the rise in viscosity caused by the dextran is less than 10mPa.s and the dextran is present in a concentration of 1 to 6g/l.

Alsop et al teach a composition containing dextrans with a molecular weight of from 10,000 to 50, 000, 000. The composition is indicated for treatment of conditions of the gastrointestinal tract (page 3, lines 20-24). The dextrans have some antibacterial action and the compositions help flow of potentially toxic or allergic substances, enabling these to pass thro the gut before they are absorbed (page 7, lines 12-22). According to Alsop et al, in general, the higher the molecular weight of the dextran the greater will be

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the viscosity (page 7, lines 4-6). Alsop et al state that the preferred liquid formulations to contain from 0.5 to 7% w/w of dextran (page 5, lines 18-19) and that the dextrans can be incorporated into existing food stuff formulation (a food supplement). Alsop et al also provide examples of compositions, which contain dextrans and other essential vitamins, and minerals, which is a complete food. Alsop discloses that no oligosaccharides (high molecular weight substances) were absorbed in volunteers fed with the dextrans (page 12, line 3).

Greenberg discloses that the primary requirement for enteral compositions is that the fiber added to the enteral composition should not substantially increase the viscosity of the product (col. 2, lines 20-25).

One of ordinary skill in the art can use the teachings of Alsop and Greenberg to make a composition containing dextran as instantly claimed. In view of the teaching of Alsop regarding the correlation between molecular weight and viscosity of dextran compositions and the preferred concentration of dextran and that of Greenberg regarding the viscosity requirement for enteral compositions, one of ordinary skill in the art can use these teachings to make a nutritional composition by adjusting the molecular weight range of the dextran and its amount in order to obtain a composition in which the amount of dextran causes a rise in viscosity which is less than 10mPa.s. as such a composition would be ideal for enteral clearance of microorganisms.

Applicant's arguments filed March 6, 2003 have been fully considered but they are not persuasive.

Applicants argue that the dextran component and the oral compositions of Alsop are used to treat constipation due to the bulking effect of the dextran and in the instant on

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the contrary the thickening effect is minimized. In Alsop's examples the concentrations are higher since a higher concentration is needed to produce the bulking effect for the treatment of constipation. Alsop also discloses that the higher the molecular weight the higher the viscosity and that the dextran compositions also enable allergic substances to pass through the gut before they are absorbed. Greenberg teaches that the soluble fiber should not substantially increase the viscosity of enteral compositions. Based on these disclosures of Alsop and Greenberg, one of ordinary skill in the art can conclude that for a composition as instantly claimed a lower concentration of dextran is essential for the desired increase or decrease of viscosity which is less than 10mPa.s.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

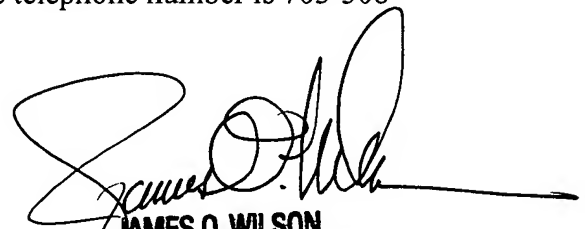
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 703-305-4837. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703-308-4624. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

GK
May 18, 2003



JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600